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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,981	10/31/2003	Sheryl E. Siegel	200.1162US	8850
7590 09/02/2009 DAVIDSON, DAVIDSON & KAPPEL, LLC 14th Floor 485 Seventh Avenue New York, NY 10018			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 09/02/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/698,981

Applicant(s)

SIEGEL, SHERYL E.

Examiner

MICAH-PAUL YOUNG

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,6,74-80,82,84,86,88 and 90-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,6,74-80,82,84,86,88 and 90-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/26/09 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 6, 74, 75, 77, 78, 80, 82, 84, 86, 89, and 91-94 are rejected under 35 U.S.C. 102(b) as being anticipated by Gonda (USPN 6,192,882 hereafter '882).

The '882 patent teaches a method for identifying a drug formulation by an associated and imparted and distinct scent, taste and color (claim 1). The method comprises imparting to a pharmaceutical dosage composition comprising a drug and a carrier a specific and distinct scent/taste that is detectable by a human or non human (col. 7, lin. 1-12). When the scent/taste particles are too small or in a low enough concentration they are no longer detectable by a human and must be detected by an electronic detection system (col. 7, lin. 14-30, col. 10, lin. 63-col. 11, lin. 38). The associated scent is stronger than the natural scent of the drug it is applied to (col. 7,

lin. 1-5). Different drug compounds are labeled and scented different in order to distinguish them from each other (col. 9, lin. 44-55). Various well known and well accepted drug compounds can be used in the practice of the invention such as insulin, analgesics and anti-inflammatory compounds (col. 9, lin. 7-13). These disclosures render the instant claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 6, 74-80, 82, 84, 86, 88, and 90-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Gonda (USPN 6,192,882 hereafter '882) in view of Peyman (USPN 5,855,907 hereafter '907).

As discussed above the '882 patent discloses a method imparting a scent to an aerosol drug dosage form for identifying purposes. The reference suggests that the method can be applied to any aerosol formulation including those for narcotics yet is silent about opioid

analgesics. The inclusion of a scent to an aerosol opioid formulation would be an obvious addition. These aerosol formulation are common in the art as seen in the '907 patent.

The '907 patent discloses an aerosol opioid formulation (abstract, col. 2, lin. 25-67). Opioids include opium and morphine compounds and derivatives (col. 3, lin. 42-45). It would have been obvious to include the scents and identifiers of the '882 patent into this formulation in order to reduce chances of overdose or misuse.

It would have been obvious to include the scent of the '882 patent and detection methods with the aerosol or topical formulation of the '907 patent in order to reduce incidents of overdose or misuse. One of ordinary skill in the art would have been motivated to make the combination with an expected result of a method of detecting the presence of delivered opioids during drug delivery.

Response to Arguments

Applicant's arguments with respect to claims 3, 6, 74-80, 82, 84, 86, 88, and 90-94 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618